SUMMARY OF THE QUALITY SYSTEMS COMMITTEE MEETING MAY 20, 1999

The Quality Systems (QS) Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met by teleconference on May 20, 1999, at 1:30 p.m. Eastern Daylight Time (EDT). The meeting was led by its chair, Mr. Joe Slayton of the U.S. Environmental Protection Agency (USEPA) Region III. A list of action items is given in Attachment A. A list of participants is given in Attachment B. There are not any entries in the list of parking lot issues at this time (Attachment C). Attachment D presents the QS Committee approach to handling comments, comment acknowledgment form letter, and commenter template. Attachment D is a listing of the QS Committee's guiding principles for reviewing comments and the standard. Changes to the language in Chapter 5 proposed at this teleconference are reflected in version 5.10.9 of the standard which is consistent with the attached comments to Dow Chemical and CBI. However, to avoid confusion within NELAC, since version 5.10.7 is the version provided for NELAC 5 voting, 5.10.9 is not attached to these minutes and will not be posted on the NELAC Website. *The purpose of the meeting was to review action items from the previous teleconferences and discuss additional comments.*

REVIEW OF ACTION ITEMS FROM THE MAY 5, 1999 MEETING BY TELECONFERENCE

The committee reviewed the action items from the May 5, 1999 meeting by teleconference. Items not already completed or addressed at today's meeting will be carried over to the next meeting.

The response to comments from Quanterra provided by Mr. Jack Hall was double checked and it was agreed that all comments had been addressed during the May 5th meeting.

It was decided that the term calibration should remain in the definition of laboratory since this is consistent with ISO 25.

The combined glossary was discussed. Apparently the QS Committee's efforts to combine Appendix B with the glossary from the Program Policy and Structure Committee was based upon a previous version of that committee's efforts. The consensus of the QS Committee was concern that other committees had suggested changes to the definitions of terms only used within Chapter 5.

Review Whole Effluent Toxicity (W.E.T.) Comments (CBI/Dr. Pete DeLisle and those from Dow Chemical/Mr. John MacLauchlan).

The discussion and consensus decision of the committee are listed in Attachment F.

In addition, the committee discussed several proposals from Dr. Fred Siegelman (related to comments from New Jersey and the Department of Defense (DOD) regarding the need for ethics training. These discussions will be continued at the next meeting.

NEXT TELECONFERENCE

The next meeting by teleconference is scheduled for May 26, 1999 from 1 p.m. to 3 p.m. EDT. The telephone number is (202)260-1015, access number 6110#.

Attachment A

ACTION ITEMS
QUALITY SYSTEMS COMMITTEE
MAY 20, 1999

Item No.	Action Item	Date to be Completed
1.	Mr. Slayton to prepare draft minutes of the teleconference.	May 25, 1999
2.	Mr. Slayton to contact the DOD (Navy-Jackie Sample) for an electronic copy of their comments.	May 25, 1999
3.	Ms. Sylvia Labie to discuss combined glossary with NELAC Board (develop a course of action).	May 26, 1999
4.	Mr. Slayton to update responses to DOW Chemical and CBI and attach them to the meeting minutes.	May 26, 1999
5.	All committee members are to review Mr. Siegelman's suggestions concerning ethics.	May 26, 1999
6.	Mr. Slayton to update the "Comments Table" to indicate current status and homework assignments and will distribute to committee.	May 26, 1999

Attachment B

PARTICIPANTS
QUALITY SYSTEMS COMMITTEE
MAY 20, 1999

Name	Affiliation	Phone Numbers
Mr. Joe Slayton	USEPA, Region III, OASQA	T: 410-305-2653 F: 410-305-2698 E: slayton.joe@epamail.epa.gov
Ms. Mary K. Bruch	Mary Bruch Micro Reg. Inc.	T: 703- 589-1514 F: 703- 779-0267 E:
Mr. Raymond J. Frederici	Recra Labnet - Chicago	T: 708-534-5200 F: 708-534-5211 E: frederir@recra.com
Mr. Clifford R. Glowacki	Ashland Chemical Company	T: 614-790-3482 F: 614-790-4294 E: cglowacki@ashland.com
Ms. Sylvia S. Labie (Board Liaison)	Florida Department of Environmental Protection	T: 904-488-2796 F: 904-922-4614 E: labie_s@dep.state.fl.us
Mr. David Mendenhall	Utah Department of Health	T: 801-584-8470 F: 801-584-8501 E: dmendenh@doh.state.ut.us
Ms. Sheila Meyers	Texas Natural Resource Conservation Commission	T: 512-239-0425 F: 512-239-6307 E: smeyers@tnrcc.state.tx.us
Mr. Jeff Nielson (Absent)	City of Tallahassee Water Quality Division	T: 850-891-1232 F: 850-891-1062 E: nielsenj@mail.ci.tlh.fl.us
Mr. Donivan R. Porterfield	Los Alamos National Laboratory	T: 505-667-4710 F: 505-665-5982 E: dporterfield@lani.gov
Mr. Scott D. Siders	Illinois Environmental Protection Agency	T: 217-785-5163 F: 217-524-0944 E: epa6113@epa.state.il.us
Dr. Fred Siegelman	US EPA, QAD	T: 202-564-5173 F: 202-564-2441 E: siegelman.frederic@epamail.epa.gov

Attachment C

PARKING LOT ITEMS/ISSUES AND FREQUENTLY ASKED QUESTIONS QUALITY SYSTEMS COMMITTEE MAY 20, 1999

Items/issues will remain in the Parking Lot until they are completed.

(There are not any items/issues outstanding at this time.)

Attachment D

ACKNOWLEDGMENT LETTER, REVIEW GUIDELINES, AND COMMENTER TEMPLATE
QUALITY SYSTEMS COMMITTEE
MAY 20, 1999

Date:

Dear :

On behalf of the Quality Systems Committee, thank you for your comments on the Chapter 5 standards of the National Environmental Laboratory Accreditation Conference (NELAC). The standards are routinely reviewed and updated. Continual improvement of the standards is the focal point of NELAC process. We encourage your continued written input as well as your attendance at the NELAC interim meeting and yearly conference. Also, our committee routinely schedules 1-2 open forum meetings during each calender year.

Our committee requests that all comments be supplied in electronic format (WordPerfect if possible) and that handwritten, hardcopy and the use of color fonts be avoided. Comments are considered by the QS committee on a first come basis. We have placed a template (table) for comments on the NELAC Web page, which we hope will ensure that the processes is efficient. With this process we hope that emphasis can be placed on consideration of the comments so that the available time is not spent in the mechanics of exchanging information (US Mail and re-typing comments). Routinely, each set of comments is assigned a QS leader who will complete the comment table including suggested language for any proposed changes to the NELAC standards. The Leader will guide a discussion of the comments during routine committee meetings. The minutes of the meeting (posted on the web site) will capture the information in the completed table from committee discussions, thoughts/rationale and present the final decisions.

Again, thank you for taking the time and effort to improve the NELAC Quality System standards.

Sincerely,
Joseph Slayton, Chair
Quality Systems Committee

QS Approach: Comments Received and QS Response:

1. A form letter will be sent to each commentor notifying them of receipt of the comment and of the QS's approach to reviewing comments and associated updates to the standards.

2. QS will consider the comments in the order received.

3. A QS committee member will be designated as the lead on each set (or up-set) of the comments from each commentor, who will provide written comments and who will lead a discussion with the full committee on any proposed changes to the standards (including providing the proposed standard language).

4. Proposed changes to the standards will be captured in the QS meeting minutes which are posted on the NELAC Web page.

5. All comments and written responses will be attached to QS meeting minutes.

6. No colors to be used in the comments nor in the response. Use double underlines for additions and strike-outs for removal of items.

7. All comments are to be provided in WordPerfect or rich text format using the following the following table:

GUIDING PRINCIPLES/REVIEW CRITERIA Attachment E

The QS Committee established a set of criteria by which to evaluate the requirements specified in Chapter 5. The standards in Chapter 5 should meet the criteria listed below:

Flexible:

Allow laboratories freedom to use their experience and expertise in performing their work and allow for new and novel analytical methods and approaches, (e.g., Performance Based Measurement System [PBMS]). That the standards specify the "What" and avoid were possible the "How To", (e.g., control limits must be developed to determine if a QC check result is acceptable, the standards do not specify how the laboratory is to determine these limits).

Auditable:

Sufficient detail is included so that the accrediting authorities evaluate laboratories consistently and uniformly.

Practical/Essential:

The standards are necessary QA policies and QC procedures and that these standards should not place an unreasonable burden upon laboratories.

Widely Applicable:

International scope- consistent with ISO Guide 25. Represent QA policies, which establish essential QC procedures, that are applicable to environmental laboratories regardless of size and complexity.

Appropriate For The Use of the Data:

Helps ensure that associated environmental data is of known quality and that the quality is adequate for the intended use of the data.

Comment ID #: , Source of Comments (Name): QS Lead on Response (Name):			
Standard Rev. # SECTION# and QS Standard Narrative (To Filled In by Commentor)	**COMMENTwith Rationale to QS (To Be Filled in my Commentor)** **New Wording for Standard (To Be Filled In by Commentor)**	**QS Leader Provided Proposed Change (Commentor Leave Blank)**	**RATIONAL (from QS Leader) (Commentor Leave Blank)**

RAY FREDERICI HOMEWORK: RESPONSE TO SECOND HALF OF COMMENTS **Attachment F**

To: Mr. Joe Slayton - Chair, Quality Systems Committee
Dr. Kathy Dien Hillig - CMA representative on ELAB

RESPONSE TO NELAC STANDARDS AS PROPOSED JANUARY 13, 1999

March , 1999

FROM: Environmental Testing Laboratories of Dow Chemical

Chapter: 5 Quality Systems

For Questions about any of these remarks, please contact either:

John MacLauchlan
Midland, MI
Phone: 517-636-5479
FAX: 517-636-5453
e-mail: jrmacl@dow.com

Richard Durham
Plaquemine, LA
Phone: 504-353-1842
FAX: 504-353-8001
e-mail: rdurham@dow.com

Standards Version Date: January 13, 1999

Section #	Comments (and suggested wording)	Committee proposal	Rationale for proposal
5.5.2	In the first line of the second paragraph of the preamble - suggest deleting "on the title page" - while the elements listed need to be in the Quality Manual & prominent, We don't think it is necessary to require all of it explicitly on the cover page. - same comment for first line under 5.5.2 (f)	No Change	The standard format will not impose significant effort/work for the laboratory but should help with the inspection of laboratories.
5.5.4 (d)	suggest adding " as required by the project goals, regulations or DQO's and " before "outlined in Appendix D"- the driver should be the DQO's, permits, etc., rather than Appendix D	**Proposed rewording**: The quality control protocols specified by the laboratory's method manual (5.10.1.2) shall be followed. The laboratory shall ensure that the essential standards outlined in Appendix D, or mandated methods or regulations (which ever are more stringent) are incorporated into their method manuals. When it is not apparent which is more stringent the QC in the mandated method or regulations is to be followed.	The QS standards are essential QC which must be followed unless those in mandated method or regulation are more stringent. If project goals require more stringent QC, this would not be a NELAC issue, i.e., would not result in a "finding" by NELAC auditors.

Chapter 5 Continued

5.9.2 (a)	There appears to be a redundant conditional statement here. Suggest deleting “wherever applicable” in second line or “where available” in third line.	5.9.2.a The overall program of calibration and/or verification and validation of equipment shall be designed and operated so as to ensure that, ~~whereever applicalbe~~, measurements made by the laboraotyr are traceabvle to national standards of measurment where availabe.	Agreed
5.9.4.1 (d)	Given our experience that balances in general are highly stable in calibration (in fact we find that weekly checks almost never show drift), why require a daily check of balances, and yet only a monthly check of mechanical volumetric dispensing devices ? We would prefer that the lab MUST define their check program, and assume the risk if it is not frequently enough to satisfy their clients.	No Change	These QC checks and frequencies are felt essential by the QS committee and though the how to do these checks is largely left to the laboratory, their in not consensus at this time to opening the frequency to the prerogative of the laboratory. However, if a laboratory finds that more frequent checks are needed by may employ more frequent checks.

5.9.4.2 (e)	We think the intent here is that the acceptance criteria be either r^2 **OR** relative % difference, not **AND** ?	"or"	Section has been rewritten
5.10.2.1(d)	If the Initial Demonstration of method performance is a measure of the overall capability of the method as practiced by the lab, then it should be independent of people changes. This is different than Initial Demonstration of Capability required for each analyst. We think "personnel" should be deleted from this section.	Section rewrites are attempting to include the concept of a work-cell (a group of analysts that together perform the analysis).	The consensus of the QS committee is that people may well be a major factor in performance of a method, and must prove that they can perform the method satisfactorily before the analysis of samples.
5.10.5 (e)	We would restate this section as " The Laboratory ID code may be the same as the field code so long as the code is unique within the lab's sample tracking system and misidentification of the sample or customer identification codes are precluded." In a "captive lab" there are regularly scheduled sampling events that may be scheduled by the lab tracking system, and the label generated by this system. The sampling time and sampler name, etc. are recorded on a chain of custody, and the lab ID becomes the internal linking mechanism.	No change but see 5.11.1 below.	The reference does not match the standard???

Chapter 5 Continued

5.11.1 (a)	see comments in 5.10.5 (e)	No change	Already allowed: see 5.11.1.e.

5.11.1 (c)	There is some concern that “durable” label means that it cannot be removed. There are many cases where the container can be cleaned for re-use, and if the label can’t be removed , there would be some problems and would increase costs	No Change	Several years ago the committee addressed this section. It revised the language to “durable label” at that time to replace “indelible ink”. The intent was to ensure the label information would sustain the rigors of sample handling during the life of the sample. This section does not specify the label requirements after sample diposal.
5.12.3.1 (n)	This section should simply say that “disposal and disposal records must be in accordance with applicable regulations and in conformance with the lab’s waste management procedures.” The records required by this section are not required by our regulators, and so should not be required by NELAC.	5.12.3.1.d: move to 5.12.3.2 5.12.3.1.e: move to 5.12.3.3 5.12.3.1.f: move to 5.12.3.3 5.12.3.1.g: delete redundant w/5.12.3.3 5.12.3.1.h: move to 5.12.3.3 5.12.3.1.i: delete redundant w/5.12.3.2 5.12.3.1.k: move to 5.12.3.3 5.12.3.1.l: move to 5.12.3.4 5.12.3.1.m: Delete	nine items listed in 5.12.3.1 are not related to the topic “sample handling” and should be moved to other sections as suggested or deleted because it is redundant with requirments in other sections.
5.12.4.1	We would suggest softening this statement. For example delete “strongly”	Already changed	The text was already deleted by the committee prior to receipt of this comment.

5.15 (c)	We are not sure what records were intended here - is this just an “approved vendors” list?	No change	This is the exact language used in ISO/IEC Guide 25 section 15.3. Appropriate records may include a list of suppliers, but also would include other records. Examples: standard/reagent purity documents, certificates of acceptablity of supplies, weight certificates, balance servicing, accreditation of subcontract laboratories, etc...
Appendix B	Analytical Reagent Grade: add the word “by” between “given” and “the”.	Change language to the definition of Analytical Reagent (AR) Grade: “designation for the high purtity of of certain reagents and solvents given by the American Chemical Society.	Clarifies language.
Appendix B	Technical Director: why not just point to Chapter 4.1.1.1 - there is an exhaustive description there	No change	Section for adds requirments for technical director. Thisis a simple definition.
Appendix D	D.1.1 (b) : Can we clarify that if MS are done that LCS are NOT required ? suggested wording: NOTE in 1): “ The matrix spike (see 2 below) may be used in place of the control, as long as ...”	Already changed	The text in the note was already edited by the committee prior to receipt of this comment.

Comments from Coastal Bionalysts, Inc.(CBI):

Proposed change:

Replace section D.2.8.f with the following: For each new batch of food used for culturing and testing, the performance of organisms fed with the new food shall be compared with the performance of organisms with a food of known quality in side-by-side tests. If the food is used for culturing, its suitability is determined using a short-term chronic test which will determine the affect of food quality on growth or reproduction of each of the relevant test species in culture, using a minimum of four replicates with each food source. Where applicable, foods used only in chronic toxicity tests are compared with a food of known quality in side-by-side, multi-concentration chronic tests, using the

reference toxicant regularly employed in the laboratory QA program. In the case of algae used as food, which is collected as a continuous batch, the quality is assessed, using side-by-side tests as described above, each time new nutrient stocks are prepared, a new starter culture is employed or when a significant change in culture conditions occurs.

Rationale:

Chemical-specific criteria for food quality cannot be applied at this time because of the lack of data regarding chronic toxicity of chemicals added to food. The criteria specified for metals and toxic organics may be over- or under protective. Additionally, toxicants may be present which are not detected by the specified analytical methods. Performance-based criteria for measuring food quality are preferred because both the presence of potential toxicants as well as nutritional quality are addressed. The EPA methods manuals, as well as other standards (e.g. ASTM E 729-96 and E 1203-92), recognize the value of performance-based criteria.

The QS committee agrees with the proposed changes to the W.E.T appendix of Chapter 5.